Medical Imaging Technology Roadmap

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WG 2 - Final Working Group Report

ULTRASOUND

Contrast Agents

1. GOALS

This section outlines the composition, role and availability of microbubble contrast agents for ultrasound, summarizes the current indications for their use, describes the impact of these agents on ultrasound scanner technology, and assesses some current areas of active development.

2. DESCRIPTION

Contrast agents for ultrasound comprise microbubbles of gas stabilized by a shell of biocompatible material such as a protein, lipid or polymer. The bubbles are smaller than red blood cells and are therefore suitable for intravenous injection. Their function is to alter the character of the scattering of blood by ultrasound, by increasing the backscatter cross-section and adding a nonlinear component. These means allow specialized imaging methods to preferentially detect the echo from the agent while suppressing that from other structures, such as solid tissue. The result is that the combination of contrast agents and new nonlinear imaging methods is capable of detecting and displaying echos from the microcirculation of, for example, the myocardium, in real time.[1]

2.1 Contrast Agents

Types of Contrast Agents
Contrast agents might act by their presence in the vascular system, from which they are ultimately metabolized ("blood pool" agents), or by their selective uptake in tissue after a vascular phase. Of the properties of tissue that influence the ultrasound image, the most

important are backscatter coefficient, attenuation and acoustic propagation velocity.[2] Most agents seek to enhance the echo by increasing the backscatter of the tissue that bears them as much as possible, while increasing the attenuation in the tissue as little as possible, thus enhancing the echo from blood. A perfect blood pool agent displays the same flow dynamics as blood itself, and is ultimately metabolized from the blood pool. Agents can be made, however, that are capable of providing ultrasound contrast during their metabolism, as well as while in the blood pool ("selective uptake" agents). Colloidal suspensions of liquids such as perfluorocarbons and certain agents with durable shells[3] are taken up by the reticuloendothelial system from which they are ultimately excreted. There, they may provide contrast from within the liver parenchyma, demarking the distribution of the Kuppfer cell. Such agents with a cell-specific pathway have the potential to be used as a means to both detect and deliver therapeutic agents to a specific site in the cardiovascular system.

Properties of an Ideal Blood Pool Contrast Agent

- Nontoxic
- Intravenously injectable, by bolus or infusion
- Stable during cardiac and pulmonary passage
- Remain within the blood pool or have a well-specified tissue distribution
- Provide a duration of effect comparable to that of the imaging examination
- Have a narrow distribution of bubble diameters
- Respond in a well-defined way to the peak pressure of the incident ultrasound

Current Formulations of Blood Pool Agents

The four methods by which contrast microbubbles are made are shown below in rough chronological order, together with their current status.

Formulation	Characteristics	Status
Free gas bubbles	Could not traverse cardiopulmonary beds	Early agents no longer used
Encapsulated air bubbles	Successful transpulmonary passage	Includes currently approved agents (e.g. Levovist™)
Encapsulated low-solubility gas bubbles	Improved stability	Includes currently approved agents (e.g. Optison™)
Particulate (e.g. polymershell) gas bubbles	Controlled acoustic properties	Under development

Summary of Principal Manufactured Contrast Agents as of October 2000

This list is not complete, but gives an indication of the widespread commitment of the pharmaceutical industry to ultrasound contrast.

Manufacturer	Name	Formulation (Shell/gas)	Development Stage
Acusphere	AI-700	Polymer/perfluorocarbon	Preclinical development
Alliance/Schering	Imavist®	Surafctant/perfluorohexane/air	Late clinical development
Bracco	SonoVue™	Phospholipid/sulphur hexafluoride	Late clinical development
Byk-Gulden	BY963	Lipid/air	Not commercially developed
Cavcon	Filmix™	Lipid/air	Preclinical development

DuPont Pharmaceutical	Definity™	Liposome/perflouoropropane	Late clinical development
Mallinckrodt Medical	Optison®	Sonicated albumin/perflouoropropane	Approved in the E.U. and U.S. for cardiology indications
Mallinckrodt Medical	Albunex®	Sonicated albumin/air	Approved in the E.U., U.S. and Canada
Nycomed	Sonazoid™	Lipid/perfluorocarbon	Late clinical development
Point Biomedical	Bisphere®	Polymer bilayer/air	Clinical development
Porter	PESDA	Sonicated albumin/perfluorocarbon	Not commercially developed
Quadrant	Quantison™	Spray-dried albumin/air	Pre-clinical development
Schering	Echovist®	Galactose matrix/air	Approved in the E.U. and Canada
Schering	Levovist®	Lipid/air	Approved in 65 countries (not the U.S.) for cardiology and radiology indications
Schering	Sonavist®	Polymer/air	Clinical development
Sonus Pharmaceutical	Echogen™	Surfactant/dodecafluoropentane	Withdrawn in October 2000

Preparation and Administration
Contrast agents may be provided ready for reconstitution by simple addition of water or saline, or they may require more elaborate preparation, such as mixing in a mechanical shaker. In all cases, the injectate must be prepared immediately before use, as the bubbles are stable for a limited time. Injection may be as an intravenous bolus in a peripheral vein, usually in the forearm. A typical injection volume varies between about 0.5 ml for Definity to about 10 ml for Levovist. In all cases, tolerance is extremely good, with more than 100 000 injections having been performed without serious adverse events. Because of the low volume of injectate, a saline flush is generally used. The effect of the bubbles is relatively brief, lasting for about three minutes for an air-based agent such as Levovist, and for about five minutes for a perfluorocarbon agent such as Optison. The duration of effect can be increased by slow injection or infusion of the agent (e.g. by a drip). Infusions can be difficult to achieve with some agents because of the tendency of the bubbles to float or dissolve upon dilution. At present, administration by infusion remains an area of research.

2.2 Indications for Ultrasound Contrast Agents
The formal indications for use of contrast agents, as new drugs, are determined by government regulation. At present, there are only a limited number of approved indications, including the following:

- enhancement of echos from nonvascular structures such as fallopian tubes;
- enhancement of Doppler signals in examinations with a poor signal-to-noise ratio (e.g. renal arteries, cardiac valves and pulmonary veins); and

- an aid to B-mode delineation of the endocardial border in echocardiographic studies of left ventricular function.

However, there is strong evidence in the literature that contrast agents can provide information about microvascular flow and perfusion not currently obtainable using conventional ultrasound techniques. Such indications include, but are not limited to the following:

- myocardial perfusion
- tumourblood supply in organs such as the breast and prostrate; and
- liver lesion detection and characterization.

2.3 Mode of Action of Microbubbles in an Acoustic Field

Microbubble contrast agents are unique in medical imaging in that they interact with the scanning process. The nature of this interaction depends on the scanning parameters, principally the peak rarefactional pressure and the ultrasound frequency. A combination of these parameters is reported by the Mechanical Index (MI), estimated and displayed on all approved scanners. At low MI, bubbles undergo resonant radial oscillation in the sound field, returning a strong echo to the transducer. At higher MI, this oscillation becomes nonlinear, so that the bubble echos contain harmonics. At the maximum MI in the diagnostic range, many bubbles are disrupted by the acoustic field, producing a strong nonlinear echo before they disappear. These three regimes of bubble behaviour are summarized in the following chart:

Peak negative pressure (approx.)	Mechanical Index (MI) @ 1 MHz	Bubble Behaviour	Acoustic Behaviour	Application
< 100 kPa	< 0.1	Linear oscillation	Backscatter enhancement	Doppler signal enhancement, cardiac cavity opacification
100 kPa to 1 MPa	0.1 to 1.0	Nonlinear oscillation	Harmonic backscatter	Coronary artery Doppler, real-time cardiac cavity opacification, real-time myocardial perfusion imaging
> 1 MPa	> 1.0	Bubble disruption	Transient harmonic echoes	Intermittent myocardial perfusion imaging, postvascular liver imaging

2.4 Impact of Contrast Agents on Scanner Design

Harmonic Imaging

The nonlinear echoes produced by ultrasound contrast agents present an opportunity to create a method that can distinguish the echoes due to contrast from those due to linear tissue. The simplest of these methods — harmonic imaging — is now widely available on ultrasound scanners. In harmonic mode, the system transmits normally at one frequency, but is tuned to receive echos preferentially at double that frequency, whereas the second harmonic echoes from where the bubbles lie. Typically, the transmit frequency lies between 1.5 and 3 MHz and the receive frequency is selected by means of a bandpass filter whose centre frequency lies between 3 and 6 MHz. Harmonic imaging uses the same array transducers as conventional imaging does, and in most of today's ultrasound systems involves only software changes. Echoes from solid tissue, as well as red blood cells themselves, are suppressed. Real-time harmonic spectral Doppler and colour Doppler modes have also been implemented on a number of commercially available systems and show a level of tissue motion suppression not available in conventional modes. Using harmonic power, Doppler flow in 40 um vessels can be detected in the moving kidney.

Pulse Inversion Imaging
Harmonic imaging imposes some fundamental limitations on the imaging process that restrict its clinical performance. These are overcome in pulse inversion imaging, in which two pulses are sent in rapid succession into the tissue; the second pulse is a mirror image of (i.e. 180° out of phase with it) the first. Echoes from linear scatterers such as tissue cancel, whereas those from bubbles do not. The resulting images show high sensitivity to bubbles at the resolution of a conventional image. Many scanners now offer some form of pulse inversion imaging.

Pulse Inversion Doppler
By detecting overlong bursts of inverted pulses and using Doppler detection methods, very high sensitivity to bubbles can be achieved so that bubbles can be detected at sufficiently low incident power levels to avoid destroying them. This opens the way to real-time perfusion imaging. Pulse inversion Doppler has demonstrated the first real-time images of myocardial perfusion using perfluorocarbon gas agents.

2.5 Cost
Cost is a potential issue for ultrasound contrast. At an approximate cost of $100 per dose, ultrasound contrast agents currently cost about as much as the ultrasound imaging examination itself. This high cost will only be justified once studies have demonstrated that the use of contrast obviates the need for a more expensive examination such as CT, MR or nuclear medicine.

3. IMPORTANCE

The addition of contrast agents to ultrasound extends the information obtainable to flow at the perfusion (i.e. arteriolar and capillary) level of the circulation. This cannot be achieved with conventional ultrasound, nor in real time, by any other currently available medical imaging modality.

4. CLINICAL REQUIREMENTS

The use of contrast agents places additional demands on the clinical use of ultrasound. These demands include upgrades to conventional ultrasound scanners, additional personnel to establish and operate the IV insertion, additional training of sonographers, and additional cost.

5. AVAILABILITY

Only some approved contrast agents are widely available. For example, of the two currently approved for use by Health Canada's Health Protection Branch — Levovist and Optison — only Levovist is marketed.

6. BREADTH OF APPLICATION

Potential areas of application of ultrasound contrast agents, in approximate rank of importance, are echocardiography, hepatic sonography, renal sonography, transcranial Doppler, breast and prostate sonography, and sonohysterosalpingiography.

Future developments in the combination of microbubble agents with drug delivery systems may take applications into intravascular (e.g. thrombolytic) therapy, chemotherapy and gene therapy.

7. IMPACT OF STANDARDS AND REGULATIONS

Regulatory approval from the relevant government agencies (in Canada, the Health Protection Branch) is required for the commercial marketing of contrast agents. In the United States, the Food and Drug Administration (FDA) is currently causing a considerable delay in the approval of contrast agents. At the time of writing, at least four agents with an "approvable" status still await final approval from the FDA. Now specific concerns over safety or efficacy have been expressed publicly. Extended delays from

the FDA could have a detrimental effect on the future of ultrasound contrast.

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Scanners

1. GOALS

Ultrasound exams are now routinely used as a diagnostic tool in almost every specialty in medicine. The popularity of ultrasound as a diagnostic modality can be attributed to its noninvasive nature coupled with the cost-effectiveness of the scanners. In the last 20 years, ultrasound scanners have made great strides in both accuracy and ease of use. Ultrasound, by definition, is a real-time imaging modality and the aim of any well-designed ultrasound scanner is to allow for rapid patient throughput without compromising diagnostic efficacy. The goal of this report is twofold:

- to understand what is currently available in ultrasound scanners; and
- to identify enabling technologies that need to be pursued to fulfil clinical and patient needs.

2. DESCRIPTION

A brief description of the technologies most useful to the generation of ultrasound images is presented in this section.

2.1 Resolution: Contrast and Spatial

Ultrasound companies are concentrating on the development of systems that provide superior contrast and detail resolution (hereinafter simply referred to as resolution). The resolution of an ultrasound system is determined by the transducer geometry, firmware and tissue characteristics of the insonated volume. In an effort to improve image quality, ultrasound companies have spent much effort on the design of better transducers and improved firmware. Today, most transducers are simple 1-D arrays that have the major drawback of being electronically steered and focussed in a single plane. Indeed, focussing in the elevation plane is normally achieved by using an acoustic lens with a fixed focus. To solve this problem, researchers have been investigating the utility of 2-D arrays that, in principle, can focus and steer in three dimensions. The development of 2-D arrays is hindered by the need to integrate a large number of small elements into an ergonomically shaped transducer. An intermediate step in the move to 2-D arrays is the development of 1.5-D arrays. These arrays have fewer elements in the elevation direction, which means that they only provide limited focussing, but no steering in this direction. The complexity and high cost of building 2-D arrays have resulted in research into the viability of using sparse 2-D arrays to achieve acceptable resolution. Another issue that must be considered with the introduction of 2-D arrays is their weight and shape. Care must be taken when designing these transducers to ensure that the likelihood of repetitive stress injury is minimized.

Already, companies such as Siemens have introduced multidimensional arrays (e.g. VFX13-5 and CX5-2). Companies such as ATL have taken a slightly different tact when it comes to improving the resolution of their systems. Using lessons learned from CT and MR, ATL's new SonoCT Real-time Compound Imaging system obtains coplanar, tomographic images from nine viewing angles, then combines them into a single image. The averaging of the nine views results in reduced speckle, clutter and noise, reinforcing real structures. The net result is images with improved resolution. Combining this technology with 2-D arrays could lead to further improvements in image quality.

2.2 Operating System and Hardware

Traditionally, ultrasound systems have been analog devices. Today, all new systems are digital, allowing for easy software upgrades. The use of custom operating systems is a thing of the past, with newer systems such as Hitachi's EUB 6000 utilizing off-the-shelf operating systems such as Microsoft's Windows NT. This enables quicker software development and allows ultrasound companies to more easily outsource development costs. Indeed, companies such as GE upgrade their systems annually. In the rapidly changing and cost-conscious health care market, there is always a need to look for ways to cut cost and speed up time to market. The move to a standard operating system will assist in meeting these requirements.

Today, processing power is becoming more and more expensive. Personal computers now possess computing power that rivals that of yesterday's mainframes. This extra computational bandwidth means that scanners can now perform more complicated

processing (e.g. 3-D or ATL's SonoCT) that would not have been possible a couple of years ago. In the future, this will allow more and more complicated protocols and features to be added to the ultrasound cart.

2.3 Software

Of crucial importance to every ultrasound clinic is the ability to improve patient throughput. Furthermore, ultrasound machines are being used more frequently in many different clinical exams. This has meant that there is a big push to improve productivity and add to a growing number of clinical protocols.

Usability Initiatives

A large push has been made to automate the setting of parameters for both B-mode and Doppler imaging. Both GE and Acuson have introduced one-touch optimization. This provides clinicians with an easy and efficient means of optimizing the system setting, thereby increasing patient throughput. Greater emphasis is being placed on user interface design with the focus on ease of use, workflow and productivity gains. Going forward, usability issues are going to become more and more important, and will be the differentiating factor between machines.

Image-guided Therapy

The use of ultrasound in image-guided radiation therapy has recently seen application to prostate and breast treatment. The real-time nature of ultrasound makes it an ideal candidate for tracking an object such as a catheter within the body. Traditionally, image-guided therapy has relied on images acquired preoperatively, which has meant that any changes in the location or structure that occur during the operation are not seen. Ultrasound can allow rapid, up-to-date visualization of *in vivo* changes. Combining ultrasound with other modalities such as CT and MR will further improve its utility as an image-guided tool.

Harmonic Imaging

Harmonic imaging is becoming an integral feature of machines from ATL, GE, Toshiba and Acuson. The advantage of this imaging is that it improves image clarity by decreasing acoustic clutter and enhancing image contrast. Harmonic imaging is useful for looking at microvasculature, and effort is being focussed on developing contrast agents with appropriate half-lives.

Wider Field of View

Siemens introduced the concept of panoramic imaging technology, which enables radiologists to instantly see expansive views of internal organs. The clinical utility of this is that it provides the clinician with better side-by-side comparisons of anatomical structures such as both lobes of the thyroid. GE has followed suit with the introduction of its LOGIQ view, which also provides functionality similar to that offered by Siemens. Improved methods of stitching images together and the application of this technology to 3-D is a very real likelihood in the near future.

3-D and 4-D Ultrasound

As noted in the Working Group 4 report *Image Analysis and Visualization* (see Section 9), 3-D visualization techniques have been used in CT for many years. To date, the application of these techniques to ultrasound is relatively immature. Based on the physics of the ultrasound signal, techniques such as surface-based rendering are not as useful. For ultrasound, multiplanar reformatting and volume rendering have proved more clinically valuable. Today, 3-D ultrasound has found most of its use in obstetrics. Indeed, 3-D ultrasound has not found its way into everyday clinical use. For this to happen, 3-D reconstruction techniques must become faster and, moreover, this functionality must become fully integrated into the scanner system. It is crucial that the use of 3-D ultrasound does not slow down the throughput of patients in the clinic. In principle, 3-D imaging has the potential to improve patient throughput by allowing the clinician to acquire a single volume that can be reformatted at any orientation — a virtual transducer, as it were. With the introduction of 2-D arrays, acquisition of 3-D volumes should be simpler and faster.

2.4 Portability

In the last decade, high-end ultrasound machines have become bigger and more complex. The need for small, portable ultrasound machines has been recognized, with companies like ATL spinning off SonoSite in 1998 to address this lucrative market. Small and affordable ultrasound scanners have the potential to reach a wider audience of clinicians and doctors. SonoSite's approach was to replace the 10–20 circuits boards found in a normal ultrasound scanner with four ASIC chips. The result is a fully functional ultrasound scanner that weighs only 2.4 kg.

More recently, a company called Terason took a different approach. Using charge-domain processing and ASIC technology, they were able to develop an ultrasound system completely housed in a scan probe. The result is a system that weighs only 10 ounces and connects to any PC computer with an IEEE 1394 (FireWire) interface.

The development of portable, low-cost ultrasound scanners is a step toward having a scanner in every doctor's office and/or clinic. In addition, these portable systems can be used in areas previously inaccessible to ultrasound scanners (e.g. battlefields and triage centers) and for rapid deployment to immobile patients.

2.5 Connectivity

Ultrasound scanners can no longer be considered stand-alone systems with no connection to the outside world. More and more hospitals are going digital, using large archives to store images. Ultrasound scanners must be able to communicate with the rest of the world. Indeed, companies such as Acuson and Agilent are offering workstation products such as KinetDx and Enconcert that offer users the ability to analyze off-line. Taking this a step further, one can expect physicians to require access to the images generated by the ultrasound machine in their office or at home via the Internet.

3. IMPORTANCE

There is a lot of competition in the ultrasound market. Medical doctors and technicians are demanding higher and higher image quality and more functionality from their ultrasound machines. Ultrasound machines are now relatively mature and soon the limits of physics will be reached. At that time, physicians will only be able to differentiate between systems based on cost and ease of use. With the health care industry becoming more and more cash constrained, it becomes important to be able to produce cost-effective ultrasound scanners while still maintaining image quality and system functionality.

4. CLINICAL REQUIREMENTS

Clinical requirements for ultrasound scanners include the following:

- real-time image capture and display;
- improved contrast and detail resolution;
- ease of use;
- connectivity via DICOM; and
- fully integrated duplex system with extensive functionality (for example, support for different transducers, harmonic imaging and in the future 3-D and even 4-D imaging for cardiology).

5. MATURITY AND RISK

Ultrasound scanners are already very mature and readily available. The existing technology provides a stable base upon which advances can be made.

6. AVAILABILITY

Ultrasound scanners of many varieties are available from many sources. Simple portable machines to very expensive systems can be obtained.

7. BREADTH OF APPLICATION

Ultrasound is used in almost all areas of medicine: obstetrics, vascular, cardiology, urology and many more. The introduction of harmonic imaging, image-guided functionality and 2-D arrays will provide additional usage for ultrasound scanners. The use of ultrasound scanners is pervasive in the medical community with no sign of diminishing.

8. IMPACT OF STANDARDS AND REGULATIONS

Standards and regulations in two areas will have an impact on what can and cannot be achieved by ultrasound scanners:

- the dosage (SPTA, TPSA, etc.) that regulatory bodies such as the U.S. Food and Drug Administration deem acceptable for certain exams; and
- DICOM working groups (e.g. WG12 and WG17) will dictate how the machine communicates data with the outside world.

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Scanner/Sonographer Interface

1. GOALS

Sonography has opened the door to many positive advances in diagnostic imaging for patients, and provided a stimulating career for sonologists (physicians) and sonographers (technologists and nurses). Unfortunately, the modality presents a health threat to the operators because of equipment ergonomics and the manner in which examinations are performed. Surveys in North America and Australia have documented health risks such as repetitive strain injury (RSI) or musculoskeletal injury (MSI), and there has been gradual recognition of the prevalence of MSI in the diagnostic ultrasound workplace. This discussion will review current concerns with ultrasound equipment design and suggest priorities for future ergonomic research and development to prevent workplace-related sonographer injuries.

Further research into causes of sonographer MSI will be valuable, as measurement of variables is difficult. For example, there is variation among sonographers with regard to

body fitness, approach to scanning technique, workstation configuration, examination duration and mix, and specialties practised.

2. DESCRIPTION

The nature of the examination and configuration of the technology (i.e. monitors, instrumentation panels and handheld transducers), including ancillary equipment (i.e. VCR, hard copy printer and camera, and electronic image file systems) will be discussed. Nontechnical equipment (such as stretchers and chairs) and the workplace environment (characterized by, for example, ambient lighting, workloads and frequency of breaks) will also be touched on.

3. IMPORTANCE

The Canadian Society of Diagnostic Medical Sonographers (Work, Health & Ergonomics Survey, Nov. 1999) reports a high prevalence of work-related musculoskeletal symptoms among respondents:

- 87 percent had pain and discomfort at some time during their career, for an average period of four years;
- majority of symptoms involved the shoulder (54 percent), neck (37 percent), wrist (25 percent) and upper back (25 percent);
- 14 percent of survey respondents with pain submitted a workers compensation claim; 61 percent of these claims were accepted; and
- 10 percent of respondents reported absence from work with an average of 25 consecutive work days missed due to MSI.

Data from a pilot study in Washington and Oregon in 1996 found that "18% of respondents suffered no symptoms, 66% suffered symptoms without RSI, and 15% have been diagnosed with RSI." The analysis revealed that a positive correlation exists between certain ergonomically unsound work habits and increased symptomatology. The proportion of sonographers diagnosed with RSI tended to increase as the number of years in the profession increased. The reporting rate of musculoskeletal symptomatology and RSI also appeared to be influenced by other variables, such as gender, workload, and stress in the workplace."

In Sydney, Australia, a survey (McFarlane 1997) of sonographers at the Royal Prince Alfred Hospital working in general, obstetrics/gynecology, and vascular and cardiac ultrasound sections revealed that 78 percent of sonographers suffered symptoms of work-related MSI.

A review of several surveys conducted in various parts of the world confirms a high incidence of MSI in the sonographer workforce. Performance of any one (or more) diagnostic ultrasound examination (i.e. echo, obstetrics, vascular, abdomen, small parts or neonatal) can lead to symptoms of MSI. Musculoskeletal symptoms are aggravated by sustained pinch grasp of small transducers, repetitive minute transducer manipulation, sustained pressure of the transducer against the patient's body, sustained shoulder abduction, sustained and repetitive twisting of the neck, trunk or both, awkward sustained postures and insufficient recovery time (breaks). Awkward posture (as with portable examinations or poor layout of an exam room), high daily workload, and years of service all play a role.

Musculoskeletal injury in the sonographer workforce with the resultant lost work days has a significant negative impact on the delivery of health care in an environment of high demand and limited resources for ultrasound services. There is a severe shortage of trained sonographers, coupled with expanding ultrasound demand due to technology advances (i.e. cardiac, vascular, musculoskeletal and interventional) in addition to increased requests for established examinations. Diagnostic ultrasound is an investigative tool used early in the diagnostic process by physicians. Lack of timely access to ultrasound resources causes treatment delays and added expense in patient diagnosis (i.e. duplication of testing, longer hospital stay and prolonged patient discomfort). To an already limited sonographer workforce and high demand, there is added the risk and impact of MSI among sonographers.

In Canada, data on workers' compensation MSI-related claims made by sonographers is not available due to the methods of data collection. However from sonographer surveys in North America, anecdotal information suggests claims do occur and are likely to increase as sonographers, employers and physicians increase their knowledge of MSI.

Aside from the issues mentioned, there is a difficult personal course of recovery and real possibility of career loss for individual sonographers suffering from MSI. Many affected sonographers continue working in pain and have a decreased ability to perform regular work duties. The pain and discomfort extend to situations outside the workplace, limiting activities at home and during recreation.

Ultrasound is an expanding technology and the need for sonographers is increasing. Ultrasound examinations are highly subjective and must be performed by trained personnel who have met a standard of practice. Managers, sonographers, and manufacturers involved in the health care industry must guard against losing sonographers to MSI.

4. CLINICAL REQUIREMENTS AND RECOMMENDATIONS

The prevention of MSI is a responsibility jointly shared by sonographers and managers. Both groups need an educated approach to MSI and to adopt preventive measures with regard to equipment placement and set up, workload and rest periods, and personal factors such as physical conditioning. Manufacturers need to be aware of MSI problems and provide user-friendly design when possible. It is recognized that perhaps there are no perfect ergonomic design solutions due to the nature of ultrasound examinations.

Given that surveys and research indicate the body regions most susceptible to MSI are the shoulders, fingers, neck and back, perhaps special attention should be given to the design of monitors, front-panel controls, and transducers and cables. Suggested design parameters are listed below by device or use.

Device	Need
Monitors	Adjustable for operator-screen distance, angle, swivel and height (sit and stand); resolution technology optimized for the human eye to discern detail without eye strain
Keyboard	Easily accessible controls; adjustable control panel positions; knobs, dials and buttons appropriate for function; minimal steps to achieve task
Transducers	Light weight cables and transducers; comfortable transducer shape for operator's grip and patient comfort; optimal cable and transducer storage
Scanner	Light weight; small size; easily maneuverable (with castors and handles); on-board storage of ancillary equipment with front-panel operation; cable management; quiet operation; low heat dispersion; footrest
Scan Bed	Bed height adjustable (21" to 32"); Trendelenburg and reverse T.; head end upright adjustable; scan beds with side rails that move under the bed, thereby facilitating patient positioning at the edge of the mattress; removable echo window cushion

5. MATURITY AND RISK

Ultrasound scanners are a product with a high degree of maturity in terms of purpose and functionality. Equipment purchase is always a compromise of features, with image quality usually the first consideration and ergonomics ranking second. The necessary

technology and knowledge exist to enhance the user-friendliness of scanners. However, it can be said that the ergonomics of sonography has not advanced significantly since the early years of real-time sonography. Purchasers need to demand that the user interface improve, and this will occur as managers become more aware of the costs of MSI.

6. AVAILABILITY

Ultrasound scanners are available from many vendors, who offer products to meet many needs. Some products offer greater ergonomic comfort than others.

7. BREADTH OF APPLICATION

The technology is applied in diagnostic medical imaging. Many medical specialties rely on diagnostic ultrasound, with examinations frequently performed by departments other than the traditional radiology department (e.g. vascular, cardiac, obstetrics and surgery).

8. COST-BENEFIT ANALYSIS

It is in the best interest of a manufacturer to design equipment to be user friendly, as it increases desirability of the product.

9. IMPACT OF STANDARDS AND REGULATIONS

Currently, regulations for ultrasound scanners apply to power output of scanners, ensuring that patients are kept safe from possible biological damage from high-frequency ultrasound (United States, Food and Drug Administration).

Regarding operator and scanner ergonomics, it is desirable that sonographer associations, vendors, and perhaps government stakeholders collaborate to develop and constantly review ergonomic guidelines for the manufacture of ultrasound scanners.

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